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Award Number: DAMD17-03-1-0454

TITLE: Increasing Breast Cancer Surveillance among African American Breast Cancer Survivors

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REPORT DATE: July 2008

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
01-07-2008	Annual	9 JUN 2007 - 8 JUN 2008

4. TITLE AND SUBTITLE

Increasing Breast Cancer Surveillance among African American Breast Cancer Survivors

5a. CONTRACT NUMBER

5b. GRANT NUMBER
DAMD17-03-1-0454

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Mount Sinai School of Medicine
New York, NY 10029

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Breast cancer survivors are at elevated risk for developing a new breast cancer compared to healthy women, and are at considerable risk for breast cancer recurrence. According to the American Society of Clinical Oncology, survivors should undergo careful breast cancer surveillance including annual mammography and breast self-exam. However, studies indicate that breast cancer surveillance among African American survivors, particularly mammography, is low, especially given the higher risk of survivors as a group. The promotion of breast cancer surveillance among African American survivors is an area that deserves special attention as cancers detected early are more treatable. One promising strategy is the adaptation of a peer-led intervention developed to increase screening among healthy African American women. The objectives of the current study are: 1) to evaluate the impact of a peer-led intervention on breast cancer surveillance intention and adherence among African American breast cancer survivors through a randomized controlled trial; and 2) to investigate the mediational pathways through which the peer-led intervention impacts surveillance intention and adherence.

15. SUBJECT TERMS
No subject terms provided.

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
					USAMRMC
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			**19b. TELEPHONE NUMBER** *(include area code)*
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Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

INTRODUCTION: Breast cancer survivors are at elevated risk for developing a new breast cancer compared to healthy women, and are at considerable risk for breast cancer recurrence. According to the American Society of Clinical Oncology, survivors should undergo careful breast cancer surveillance including annual mammography and breast self-exam. However, studies indicate that breast cancer surveillance among African American survivors, particularly mammography, is low, especially given the higher risk of survivors as a group. The promotion of breast cancer surveillance among African American survivors is an area that deserves special attention as cancers detected early are more treatable. One promising strategy is the adaptation of a peer-led intervention developed to increase screening among healthy African American women. The objectives of the current study are: 1) to evaluate the impact of a peer-led intervention on breast cancer surveillance intention and adherence among African American breast cancer survivors through a randomized controlled trial; and 2) to investigate the mediational pathways through which the peer-led intervention impacts surveillance intention and adherence. 409 participants will be recruited and randomized over the course of the study. Participants will be African American women age 20-74 years and diagnosed with Stage I, II or III breast cancer who previously participated in an ongoing parent project and are at least 3 months post-treatment. Once informed consent is obtained, participants will be contacted via telephone to complete a baseline interview assessing sociodemographic information, breast cancer surveillance intention and adherence, and attitudinal/cognitive variables. Participants will then be assigned to either the survivor surveillance intervention condition or control condition and those in the intervention condition will participate in the intervention. One month following the intervention, participants in both conditions will complete a telephone interview to assess breast cancer screening adherence and changes in attitudinal/cognitive variables from baseline to post-intervention. Fourteen months after the intervention, women in both conditions will be contacted again in order to assess surveillance intention and adherence.

BODY: In June 2007, a one-year no-cost extension was granted. In April of 2008, a change to the SOW was approved. The change in SOW was requested for the following reasons:

1) Initial challenges in study start-up and amendment approval: The performance period began June 2003 but due to the link between the current grant and a parent grant, DOD IRB approval was not received until November 2004. Amendments to expand recruitment strategies proposed April 2006 and approved by DOD IRB in December 2006.

2)Resources absorbed by unplanned expansion of recruitment strategies: Due to delays in study start-up, it became necessary to expand recruitment strategies. Initially recruitment was based on MSSM COE Project 1. However, it became apparent that this project would not suffice as an exclusive referral source since it focused on recruiting newly diagnosed patients, resulting in a substantial lag-time as the current grant requires that a patient be at least 3 months post-treatment. We expanded our recruitment strategies by identifying site PIs and opening protocols at two local hospitals: New York Hospital Queens and Kings County Hospital Center. This demanded a significant allocation of the study's human resources in order to navigate the IRBs of these hospitals as well as work with site PIs and staff to identify potential patients. We also expanded our recruitment strategies by combining recruitment efforts with two other research studies targeting a similar patient population, which required approximatley10 external visits and/or presentations at hospitals, clinics, and breast cancer survivor support groups.

3) Higher refusal rates than anticipated: After expanding our recruitment strategies, we identified 312 survivors who were part of the total recruitment pool. Of these, 197 ineligible, deferred, death, hospitalization, unable to contact, otherwise excluded. Of those who were eligible and contacted, there were 53 refusals, resulting in a refusal rate of 46%

4) Low SIS intervention attendance: In total, 62 women were agreed to participate in the study and 2 were dropped from baseline analyses. There were 31 in intervention group and 29 in control group. Between 2004

and April 2007, 12 SIS programs were scheduled. However, only 20 participants attended interventions, resulting in a no-show rate of 36%. We were not able to increase the intervention rate even after applying certain strategies, including changes in the location of intervention programs, serving refreshments, and including raffles and give-aways. This raised serious concerns about the feasibility and practicality of the intervention.

5) Ceiling effects: Enrolled participants reported high adherence to ASCO guidelines at baseline. In our sample, 92% were adherent to mammography guidelines (32% reported at baseline that they had an upcoming appointment for a mammogram). According to our statistical consultant, with a base rate of 92%, a sample size 552 women would be required to observe a 4%increase in mammography use (92% to 96%). Eight-six percent reported adherence to physical exam (49% reported at baseline that they had an upcoming appointment for a physical exam at baseline). Observation of a 4% increase in adherence to physical exam (from 86% to 90%) would require a sample size of 1035. Finally, 76% reported adherence to pelvic exam/pap test (23% reported an upcoming appointment at baseline). For a 5% increase in these tests (76% to 81%), a sample of 1059 women would be required. Participants also demonstrated high baseline scores on most mediating variables including knowledge about recurrence & post-treatment surveillance, perceived advantages of surveillance, and reported intention to have a mammogram and physical exam.

6) New research opportunity: In order to address the feasibility concerns discussed above, we sought and obtained funding in 2007 through the Susan G. Komen for the Cure Breast Cancer Disparities Research Award to convert the live SIS intervention into DVD format (performance period 9/21/07 – 9/20/09). The aims of this new study are 1) to develop a DVD intervention based on SIS to promote post-treatment breast cancer surveillance among African American breast cancer survivors that is guided by focus group input; 2) to conduct a pilot evaluation of the cognitive and psychological impact of the SIS-DVD intervention using standardized questionnaires; and 3) to disseminate results of the SIS-DVD evaluation via educational seminars targeting African American breast cancer survivors as well as healthcare providers and advocacy groups. After initial production of the SIS-DVD, we will conduct two focus groups of AA breast cancer survivors to obtain feedback using standard focus group methods. Once this feedback is analyzed, these results will guide the final edit of the SIS video to be used in the questionnaire component of the project. In this component, 60 AA breast cancer survivors will be a recruited through physician referral. These participants will complete a single pre-test/intervention/post-test session.

As part of the revised SOW, we will add a new component in which we will test the impact of the SIS DVD intervention among 120 African American breast cancer survivors by comparing 2 randomized groups at baseline and 6-month follow-up: 1) participants shown the SIS DVD intervention and 2) participants shown a control health DVD intervention.

The revised SOW is as follows:

I. Months 1-17

b. Hire and train research staff
c. Develop live, peer-led intervention: Survivors in Spirit (SIS)
    1. Recruit and coordinate an advisory board to provide feedback on intervention content
d. Prepare peer interventionists
    1. Identify and recruit survivors and non-diagnosed women as interventionists
    2. Conduct group and individual training sessions
    3. Evaluate impact of training curriculum
e. Collaborate with co-investigators and consultants to review assessment strategies and tailoring of the survivor surveillance intervention
    1. Pilot test and refine measures

f. Develop data entry and participant tracking systems

II. Months 18 - 32

A. Review database of parent project to identify eligible breast cancer patients
a. Recruit and consent 60 patients for randomized controlled trial via telephone
b. Administer baseline assessment and 1 –month follow-up interview for randomized controlled trial via telephone
c. Randomize participants and coordinate SIS intervention programs
    1. Identify appropriate SIS program sites
    2. Coordinate a team of peer interventionists for each SIS program
    3. If necessary, provide transportation for interventionists and participants
    4. Collect data on immediate post-intervention evaluation from study participants
d. Commence data entry and management

III. Months 32-38

A. Expand recruitment strategies via outreach to New York Hospital Queens and Kings County Hospital
    1. Identify site PIs
    2. Obtain site IRB approvals
    3. Collaborate with site PIs to review patient charts and tumor registries to identify potential patients
    4. Continue recruitment efforts
B. Collaborate with other studies to promote individual referral from other sites
    1. Conduct informational presentations at hospitals, clinics, and survivor advocacy group meetings

IV. Months 32-48

a. Commence contact of participants via telephone to administer 14-month follow-up assessment interviews
b. Continue data entry and management
c. Work with co-investigators and consultants to conduct analyses for report
d. Prepare manuscripts for publication

VI. Months 49 - 78

A. Re-assess feasibility of live peer intervention
B. Use data from intervention development, baseline and follow-up assessments to develop a DVD intervention based on SIS (Currently funded by Susan G. Komen for the Cure 9/21/07 – 9/20/09).
C. Develop DVD intervention
D. Obtain feedback on DVD content via focus groups
E. Evaluate the impact of the DVD on cognitive and emotional outcomes among 60 African American breast cancer survivors in a single pre-test/intervention/post-test session.
F. Test the impact of the DVD intervention among 120 African American breast cancer survivors by comparing 2 randomized groups at baseline and 6-month follow-up
    1. Participants shown the SIS DVD intervention
    2. Participants shown a control health DVD intervention

KEY RESEARCH ACCOMPLISHMENTS: There are no key accomplishments to report for the past study year. In terms of the new focus of work under months 49-78, we are currently awaiting local IRB approval.

REPORTABLE OUTCOMES: See revised SOW above.

CONCLUSIONS: Findings suggest that the feasibility of the SIS program is limited by 1) difficulty in the continual assembling of audiences of survivors appropriate for SIS presentations as demonstrated in a high "no-show" rate, and 2) the high cost and labor-intensiveness of assembling teams of lay health educators for SIS presentations. These are problems important to address in order to disseminate SIS beyond the research context. The conversion of SIS into a DVD (digital video disc) directly addresses these problems by making SIS content available to individual survivors in an easily disseminated form.exposure to the post-treatment surveillance intervention results in increases in knowledge about recurrence and post-treatment surveillance, perceptions of the benefits of post-treatment surveillance, and stronger intentions to participate in necessary mammography screening, physical exams, and BSEs.